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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,909	11/28/2001	Torleif Ove Bjornson	50225-8028.US03	4128
22918	7590	11/22/2004	EXAMINER	
PERKINS COIE LLP			NOGUEROLA, ALEXANDER STEPHAN	
P.O. BOX 2168				
MENLO PARK, CA 94026			ART UNIT	PAPER NUMBER

1753

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MLK

Office Action Summary

Application No.

09/995,909

Applicant(s)

BJORNSEN ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 9-16, 23, 24, 26-30, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrow et al. (US 5,976,336) ("Dubrow").

Addressing claim 9, Dubrow discloses a microfluidic device, comprising
a body structure (300) comprising a main channel (100,304) and a sample-loading channel fabricated therein (102,314), the main channel intersecting the sample-loading channel (Figures 1A and 3), which sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir (110,316); and,

a transport system coupled to the sample loading channel, the transport system comprising one or more control devices which direct movement of the at least one sample

material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel (col. 7, ll. 20-25 and col. 10, ll. 47-52), which one or more control devices concomitantly direct flow of material through the main channel (col. 7, ll. 25-49 and col. 10, ln. 61 – col. 11, ln. 11).

Addressing claim 10, Dubrow does not *mention* an instruction set as claimed, but such an instruction set is inherent in Dubrow because the voltages are applied to the device to inject the at least one sample material into the main channel and electroosmotically or electrophoretically flow the resulting injected sample through at least a portion of the main channel while simultaneously preloading an additional sample into the sample loading channel (col. 7, ll. 43-49 and col. 11, ll. 3-7).

Addressing claim 11, Dubrow discloses preloading and electrophoretically flowing several different samples. See Figure 2B.

Addressing claim 12, a plurality of reservoirs as claimed may be seen in Figures 1A and 3.

Addressing claims 13-16, a plurality of reservoirs as claimed may be seen in Figure 3.

Addressing claim 23, note, for example 324, 332, 326, and 334 in Figure 3.

Addressing claim 24, for the additional limitation of this claim see col. 7, ll. 57-59 and col. 10, ll. 35-38.

Addressing claims 26 and 27, for the additional limitations of these claims see col. 12, ll. 36-40.

Addressing claim 28, for the additional limitations of this claim see Figures 1 and 3 and col. 7, ll. 30-49 and col. 11, ll. 3-39.

Addressing claims 29 and 30, for the additional limitations of this claim see col. 3, ll. 4-29 and col. 5, ll. 2-12.

Addressing claims 33 and 34, for the additional limitations of these claims see col. 9, ll. 64-67.

Addressing claim 35, at least a voltage regulator and a pressure regulator of hydrodynamic regulator as claimed are disclosed. See col. 10, l. 35-46

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrow et al. (US 5,976,336) ("Dubrow").

Addressing claims 17-19, Dubrow discloses a microfluidic device, comprising

a body structure (300) comprising a main channel (100,304) and a sample-loading channel fabricated therein (102,314), the main channel intersecting the sample-loading channel (Figures 1A and 3), which sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir (110,316); and,

a transport system coupled to the sample loading channel, the transport system comprising one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel (col. 7, ll. 20-25 and col. 10, ll. 47-52), which one or more control devices concomitantly direct flow of material through the main channel (col. 7, ll. 25-49 and col. 10, ln. 61 – col. 11, ln. 11).

Dubrow does not *mention* having the reservoirs arranged on 9 mm, 4.5 mm, or 2.25 mm centers, which the examiner interprets as meaning that adjacent reservoir centers are 9 mm, 4.5 mm, or 2.25 mm apart. However, Dubrow does disclose dimensions for the device on the order of millimeters and that “larger or smaller devices may also be prepared depending upon the number of analyses that are to be performed, and the desired volume of the reagent reservoirs.” See col. 4, ll. 59-67 and col. 11, ll. 46-64. Barring evidence to the contrary, such as unexpected results, the spacing between the reservoirs is a design choice based on the size of the reservoirs and how compact the device is to be made; that is, the practical density or number of reservoirs per unit area of the device. Also see col. 6, ll. 16-33; col. 9, ll. 25-28; and MPEP 2144.04.IV.A.

Addressing claims 20-22, Dubrow discloses a microfluidic device, comprising a body structure (300) comprising a main channel (100,304) and a sample-loading channel fabricated therein (102,314), the main channel intersecting the sample-loading channel (Figures 1A and 3); which sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir (110,316); and,

a transport system coupled to the sample loading channel, the transport system comprising one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel (col. 7, ll. 20-25 and col. 10, ll. 47-52), which one or more control devices concomitantly direct flow of material through the main channel (col. 7, ll. 25-49 and col. 10, ln. 61 – col. 11, ln. 11).

Dubrow does not *mention* having the reservoirs arranged at a density greater than about 2 reservoirs per centimeter², or greater than about 4 reservoirs per centimeter², or greater than about 8 reservoirs per centimeter². However, Dubrow does disclose having the reservoirs compactly arranged in an area the order of millimeters² and that “larger or smaller devices may also be prepared depending upon the number of analyses that are to be performed, and the desired volume of the reagent reservoirs.” See col. 4, ll. 59-67 and col. 11, ll. 46-64. Barring evidence to the contrary, such as unexpected results, the spacing between the reservoirs is a design choice based on the size of the reservoirs and how compact the device is to be made; that is, the practical density or number of reservoirs per unit area of the device. Also see col. 6,

II. 16-33 and MPEP 2144.04.IV.A.

Addressing claim 25, Dubrow discloses a microfluidic device, comprising a body structure (300) comprising a main channel (100,304) and a sample-loading channel fabricated therein (102,314), the main channel intersecting the sample-loading channel (Figures 1A and 3), which sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir (110,316); and,

a transport system coupled to the sample loading channel, the transport system comprising one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel (col. 7, ll. 20-25 and col. 10, ll. 47-52), which one or more control devices concomitantly direct flow of material through the main channel (col. 7, ll. 25-49 and col. 10, ln. 61 – col. 11, ln. 11).

Dubrow does not *mention* channels having approximately the same width and depth (a square cross-section), although Duborw does a channel having a rectangular cross-section. See col. 12, ll. 36-40. Barring evidence to the contrary, such as unexpected results, the shape of the cross-section of the channels, especially a square cross-section instead of a rectangular cross-section, is merely a change in shape, which in itself is not obvious. MPEP 2144.04.IV.B.

7. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrow et al. (US 5,976,336) (“Dubrow”) in view of Pace (US 4,908,112) (“Pace”).

Addressing claim 31, Dubrow discloses a microfluidic device, comprising a body structure (300) comprising a main channel (100,304) and a sample-loading channel fabricated therein (102,314), the main channel intersecting the sample-loading channel (Figures 1A and 3), which sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir (110,316); and,

a transport system coupled to the sample loading channel, the transport system comprising one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel (col. 7, ll. 20-25 and col. 10, ll. 47-52), which one or more control devices concomitantly direct flow of material through the main channel (col. 7, ll. 25-49 and col. 10, ln. 61 – col. 11, ln. 11).

Dubrow discloses making a second substrate from one of various plastics claimed by Applicants, glass, or silicon. See col. 3, ll. 4-29 and col. 5, ll. 2-12. Dubrow does not mention a first substrate overlaid over the second substrate made wherein the first substrate and the second substrate are independently selected from the claimed materials. Pace discloses a micro fluidic device comprising a second substrate made of silicon and a first substrate made of glass overlaid over the second substrate. See col. 6, ll. 24-27 and col. 6, ll. 46-49. If the second substrate in Dub row is made of silicon (col. 4, ll. 31-48), it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the first substrate made of

glass as taught by Pace in the invention of Dubrow because as taught by Pace a glass substrate will allow optical monitoring of migrating molecules in the channels. See col. 5, l. 60-66.

Addressing claim 32, it should be first noted that this claim only has a product-by-process limitation and so does not further limit claim 31 unless a material difference is shown between the invention of Dubrow as modified by Pace. In any event, etching is disclosed in col. 12, ll. 36-39 of Dubrow and in col. 7, ll. 14-30 of Pace.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
November 18, 2004